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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/966,863 | 09/28/2001 | Jeffrey A. Wolk | 100/06110 | 7390 |
| 21569 | 7590 | 08/12/2005 | EXAMINER | |
| CALIPER LIFE SCIENCES, INC. 605 FAIRCHILD DRIVE MOUNTAIN VIEW, CA 94043-2234 | | | OLSEN, ALLAN W | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1763 | |
| DATE MAILED: 08/12/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/966,863 | WOLK ET AL. | |
| | Examiner | Art Unit | |
| | Allan Olsen | 1763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005 and 20 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 3,4 and 10-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9/28/01</u> . | 6) <input type="checkbox"/> Other: _____ |

LR *KE*

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1, 2 and 5-9, in the reply filed on June 6, 2005 is acknowledged.

Claims 3, 4 and 10-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in replies filed on September 20, 2004 and June 6, 2005.

Information Disclosure Statement

Upon review of the file the examiner has noted that an information disclosure statement was filed on September 28, 2001. Copies of the references were not provided because this is a divisional application and the references should be available in the parent application file. However, the parent application file does not contain the cited references. As indicated on the attached copy of the IDS, the foreign patent and non-patent literature has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Regarding claim 2, the examiner finds no support in the specification for using a tool to create an aperture in a silica-based substrate. Rather, the specification associates the patterning of silica-based substrates with etching.

Regarding claim 9, the examiner finds no disclosure to support claims directed to a process in which a capillary is inserted into an aperture in the second substrate layer in conjunction with aligning a tool with an alignment mark in the first substrate and using the tool to create an aperture in the first substrate.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the phrase "the first surface of the first substrate ". There is insufficient antecedent basis for this limitation in the claim. This may be remedied by reciting -- a first surface of the first substrate layer--.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,224,830 issued to Harrison et al. (hereinafter, Harrison)

Harrison teaches drilling an aperture in a first substrate layer of a microfluidic device. Harrison teaches bonding a first and second substrate layers together such that an aperture in the second substrate layer corresponds to the aperture in the first substrate layer. Harrison teaches inserting a capillary element into the aperture.

Harrison does not teach aligning the drill with an alignment structure in the first substrate.

It would have been obvious to one skilled in the art to align the drill with an alignment structure because the skilled artisan would readily appreciate that the micro scale of Harrison's channels would necessitate very accurate drilling and the use of alignment structures is a fundamental machining technique, with the drilling of a pilot hole or the use of a center punch, prior to drilling, being two such examples.

Claims 1 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison in view of US Patent 6,605,472 issued to Skinner et al. (hereinafter, Skinner)

Harrison teaches drilling an aperture in a first substrate layer of a microfluidic device. Harrison teaches bonding a first and second substrate layers together such that

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an aperture in the second substrate layer corresponds to the aperture in the first substrate layer. Harrison teaches inserting a capillary element into the aperture.

Harrison does not teach aligning the drill with an alignment structure in the first substrate.

Skinner teaches a two-step process of drilling an aperture in a microfluidic device. The first and second steps use a different drill bit. The first step uses a pointed drill bit and effectively creates an alignment structure/pilot hole that is used in the second drilling step.

It would have been obvious to one skilled in the art to use the two-step drilling process of Skinner when drilling the aperture of Harrison because Skinner's two-step process creates a capillary junction with minimal dead volume.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new grounds of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

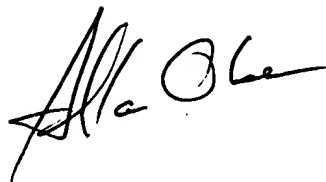
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allan Olsen whose telephone number is 571-272-1441. The examiner can normally be reached on M-F 1-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Parviz Hassanzadeh can be reached on 571-272-1435. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Allan Olsen', with a stylized flourish at the end.

Allan Olsen
Primary Examiner
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